Filing Date: September 30, 2003

Title: DRUG-ELUTING ELECTRODE

IN THE CLAIMS

Please amend the claims as follows:

- 1. (Currently Amended) An apparatus comprising:
 - an electrical lead comprising a lead body and an electrical conductor; and
 an electrode coupled to the electrical conductor, wherein the electrode includes a coating

on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent.

- 2. (Original) The apparatus of claim 1, wherein the electrode includes a helical tip.
- 3. (Original) The apparatus of claim 1, wherein the pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 4. (Original) The apparatus of claim 3, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 5. (Original) The apparatus of claim 1, wherein the first layer comprises a polymeric base coat on the electrode surface and the second layer comprises a matrix including a polymer and at least one pharmacological agent, wherein the second layer at least partially covers the polymeric base coat.
- 6. (Original) The apparatus of claim 5, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.

- 7. (Original) The apparatus of claim 6, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 8. (Original) The apparatus of claim 5, wherein the polymeric base coat is ethylene vinyl alcohol.
- 9. (Original) The apparatus of claim 1, further comprising a third layer above the second layer, wherein the third layer includes a porous barrier.
- 10. (Original) The apparatus of claim 9, wherein the porous barrier comprises a polymeric coating.
- 11. (Currently Amended) The apparatus of claim 9, wherein the second layer comprises a matrix including a polymer and at least one pharmacological agent and the third layer regulates the release of the pharmacological agent from the second layer matrix.
- 12. (Original) The apparatus of claim 1, further comprising an outer layer, wherein the outer layer includes at least one pharmacological agent.
- 13. (Original) The apparatus of claim 12, wherein the pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 14. (Original) The apparatus of claim 13, wherein the anti-inflammatory agent is dexamethasone, clobetasol, becomethasone, or a pharmaceutically acceptable salt thereof.
- 15. (Original) The apparatus of claim 1, wherein the first layer is adapted to functionally increase an impedance of the electrode.

- 16. (Previously Presented) A system comprising:
 - an electrical pulse generator;
- an electrical lead releasably coupled to electrical pulse generator, wherein the electrical lead includes a lead body and an electrical conductor; and
- an electrode coupled to the electrical conductor, wherein an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent.
- 17. (Original) The system of claim 16, wherein the electrode includes a helical tip.
- 18. (Original) The system of claim 16, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 19. (Original) The system of claim 18, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 20. (Original) The system of claim 18, wherein the anti-inflammatory agent is dexamethasone.
- 21. (Previously Presented) The system of claim 16, wherein the first layer comprises a polymeric base coat on the electrode surface and the second layer comprises a polymer and at least one pharmacological agent matrix on the polymeric base coat.
- 22. (Original) The system of claim 21, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 23. (Original) The system of claim 22, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.

24. (Original) The system of claim 21, wherein the polymeric base coat is ethylene vinyl

alcohol.

25. (Original) The system of claim 21, further comprising a third layer, wherein the third layer comprises a porous barrier.

26. (Original) The system of claim 25, wherein the third layer regulates the release of the pharmacological agent from the matrix.

27. (Original) The system of claim 25, further comprising a fourth layer, wherein the fourth layer comprises at least one pharmacological agent.

28. (Original) The system of claim 27, wherein the pharmacological agent of the fourth layer comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.

29. (Original) The system of claim 28, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.

30. (Previously Presented) An apparatus comprising:

an electrical lead comprising a lead body and an electrical conductor; and

an electrode coupled to the electrical conductor, wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including three or more layers, with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of the pharmacological agent and an outer layer including only a pharmaceutical agent such that the pharmaceutical agent of the outer layer is exposed to tissue upon implant of the electrode, and a middle layer between the inner layer and the outer layer, the middle layer including a porous polymer barrier.

31. (Original) The apparatus of claim 30, wherein the electrode includes a helix.

32. (Original) The apparatus of claim 30, further including a third layer directly adjacent a surface of the electrode comprising a polymer primer layer, with the inner layer adjacent the polymer primer layer.

- 33. (Original) The apparatus of claim 30, wherein the pharmaceutical agent in the polymer matrix includes an anti-inflammatory drug.
- 34. (Original) The apparatus of claim 30, wherein the pharmaceutical agent in the polymer matrix includes an anti-proliferative drug.
- 35. (Currently Amended) A method comprising:

coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat: and

coating the <u>first layer of the</u> electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer.

- 36. (Original) The method of claim 35, wherein the pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 37. (Original) The method of claim 36, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 38. (Original) The method of claim 35, wherein the polymeric base coat is ethylene vinyl alcohol
- 39. (Original) The method of claim 35, further comprising a third layer, wherein the third layer comprises a porous barrier.

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40. (Currently Amended) The method of claim 39, wherein the second layer comprises a matrix including a polymer and at least one pharmacological agent and the third layer regulates the release of the pharmacological agent from the second layer matrix.

- 41. (Original) The method of claim 35, further comprising an outer layer, wherein the outer layer comprises at least one pharmacological agent.
- 42. (Original) The method of claim 41, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 43. (Original) The method of claim 42, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 44. (Previously Presented) The method of claim 35, wherein the coating is applied by contacting the exterior of the electrode with a composition comprising at least one polymer and at least one pharmacological agent.
- 45. (Original) The method of claim 44, wherein the contacting includes spraying.